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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/069,561 | 10/22/2001 | Yoshio Jo | 763-29 | 3304 |
| 28249 | 7590 | 06/06/2005 | EXAMINER | |
| DILWORTH & BARRESE, LLP 333 EARLE OVINGTON BLVD. UNIONDALE, NY 11553 | | | OH, SIMON J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |

DATE MAILED: 06/06/2005

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/069,561
Filing Date: October 22, 2001
Appellant(s): JO ET AL.

George M. Kaplan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 02 December 2004.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The appellant has stated in the brief there are no related appeals or interferences that would directly affect or be directly affected by or have a bearing on the decision in the pending appeal.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

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(7) Grouping of Claims

The rejection of claims 34, 36-55, 57-60, and 62-74 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

| | | |
|-----------------|------------------|---------|
| EP 0 956 869 A2 | SOE et al. | 11-1999 |
| 4,340,731 | COLUMBO et al. | 07-1982 |
| 5,962,026 | EDWARDSON et al. | 10-1999 |
| 4,265,233 | SUGITACHI et al. | 05-1981 |

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 34, 36-55, 57-60, and 62-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soe *et al.* in view of Columbo *et al.*, Edwardson *et al.*, and Sugitachi *et al.*

The Soe *et al.* reference discloses a tissue sealant that comprises carboxymethyl cellulose, with a degree of etherification of preferably 0.5% to 1.5% and most preferably 0.6% to 0.8% (See Sections [0016] to [0017]). The sealant preferably further comprises enzymes such as thrombin, and proteins, which include fibrinogen and coagulation factor XIII. All components of

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the tissue sealant are biodegradable (See Sections [0015] and [0029]). A method of preparing the tissue sealant is disclosed (See Section [0039]).

The Soe *et al.* reference does not disclose the chemical bonding of proteins to cellulosic fibers through treatment with carbodiimide, nor does the reference disclose a process for the etherification of low-substituted cellulose fibers, nor does it teach a tissue sealant in the form of a fiber or fabric.

The Columbo *et al.* patent teaches a process for etherification of cellulose fibers into soluble carboxymethyl cellulose. The fibers are treated with a solution of sodium hydroxide and further treated with a monochloro acetic acid solution to form carboxymethyl cellulose with a degree of substitution equal to 0.8, and then dried. (See Column 6, Example 3). It is further disclosed that the treated cellulose is suitable for use in bandages (See Column 6, Line 66 to Column 7, Line 2).

The Edwardson *et al.* patent teaches a fibrin composition useful as a surgical sealant to provide hemostasis (See Abstract). The patent discloses that a thrombin-like enzyme may be immobilized on a support through various activation chemistries, including carbodiimide groups. Suitable supports for immobilization include cellulose and cellulose derivatives (See Column 8, Line 63 to Column 9, Line 35).

The Sugitachi *et al.* patent discloses materials for wound healing having Factor XIII and thrombin affixed to it (See Abstract; and Column 3, Lines 18-40). The material further comprises a structure which may take various forms, including cotton, non-woven fabrics, woven fabrics, knitted fabrics, twisted yarns, knitting yarns, bandages, and burn dressings, as well as absorbable materials. Natural polymers may be used to make up these structures,

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including cellulose, carboxymethyl cellulose, and methylcellulose (See Column 1, Line 39 to Column 2, Line 4). Factor XIII and thrombin may be fixed to a structure in forms such as a monofilament, a fibrous assembly, a film, or a sponge (See Column 3, Lines 36- 41). Examples are disclosed where surgical gauze was treated and then imparted with Factor XIII and thrombin (See Examples 1 and 2). The material is described as being useful for protecting a wound site and promoting the formation of fibrin for long periods of time (See Column 8, Lines 55-68).

It would have been obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the references of the prior art into the object of the rejected claims. Edwardson *et al.* provides a motivation, disclosing that immobilization of a thrombin-like enzyme can prevent contamination of the composition (See Edwardson *et al.*, Column 8, Lines 57-62). The Soe *et al.* patent states that the use of low-substituted carboxymethylcellulose is preferred for the disclosed invention. Therefore, one of ordinary skill in the art would seek to find methods of producing low-substituted cellulose ether in order to carry out the best mode of the invention described in the Soe *et al.* patent. The Columbo *et al.* patent discloses such methods of production. From there, further treatment of the material with carbodiimide according to Edwardson *et al.* may be carried out for the reasons described above. One of ordinary skill in the art would have been motivated to combine the disclosure of Sugitachi *et al.* with that of Soe *et al.* so as to provide a suitable vehicle for substances such as Factor XIII and thrombin that is also capable of protecting a wound site. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court

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explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art.” In this case, both the *Soe et al.* and *Sugitachi et al.* references deal with wound-treating compositions that may comprise carboxymethyl cellulose, thrombin, and Factor XIII. With the combined disclosure of the prior art, it becomes obvious to one of ordinary skill in the art that carboxymethyl cellulose, as a vehicle for substances such as thrombin, fibrinogen, and Factor XIII, can take various forms, including the sealant of *Soe et al.*, the fibers of *Columbo et al.*, and the fabrics and monofilaments as disclosed in *Sugitachi et al.* Furthermore, it is the position of the examiner that as the collective disclosure of the prior art has made obvious the instantly claimed invention, claimed features, such as fibrinomer absorptivity, maximum platelet agglutination rate, agglutination percentage, adhered cell count, and mean hemostasis time, would be present as well. As a composition cannot be separated from its properties, so it is that the prior art, having disclosed the same composition with the same components would also possess the same characteristics as claimed by the appellant, even if the prior art is silent with respect those characteristics. Thus, the instantly claimed invention is *prima facie* obvious.

(11) Response to Argument

(A) In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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In this case, the breadth of the claims, as characterized by the use of the transitional phrase “comprising” permits a broad approach to the instantly claimed subject matter by the examiner. The deciding factor in this case is that the prior art references broadly deal with the same field of endeavor to solve the same problem, that is, wound healing.

As explained above, the Soe *et al.* patent states that the use of low-substituted carboxymethylcellulose is preferred for the disclosed invention. Therefore, one of ordinary skill in the art would seek to find methods of producing low-substituted cellulose ether in order to carry out the best mode of the invention described in the Soe *et al.* patent. The Columbo *et al.* patent discloses such methods of production. From there, further treatment of the material with carbodiimide according to Edwardson *et al.* may be carried out by the motivation therein, that immobilization of a thrombin-like have been motivated to combine the disclosure of Sugitachi *et al.* with that of Soe *et al.* so as to provide a suitable vehicle for substances such as Factor XIII and thrombin that is also capable of protecting a wound site. In this case, both the Soe *et al.* and Sugitachi *et al.* references deal with wound-treating compositions that may comprise carboxymethylcellulose, thrombin, and Factor XIII. With the combined disclosure of the prior art, it becomes obvious to one of ordinary skill in the art that carboxymethyl cellulose, as a vehicle for substances such as thrombin, fibrinogen, and Factor XIII, can take various forms, including the sealant of Soe *et al.*, the fibers of Columbo *et al.*, and the fabrics and monofilaments as disclosed in Sugitachi *et al.* In the particular instance, the examiner interprets the disclosure of monofilaments in the Sugitachi *et al.* reference to sufficiently read on the appellants' claimed fiber.

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(B) In response to appellant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

The appellant has stated that the degree to which a large number references may be successfully combined to fashion an obviousness rejection must be decided upon the facts of each case. Further, the appellant argues that when the number of references is considered within the context of the other arguments and evidence set forth, then it allegedly lends a patentable unobviousness to the instantly claimed invention.

However, the appellant has failed to specifically identify which facts in the case would provide sufficient rebuttal against the number of references used in the obviousness rejection of record. Likewise, no specific argument or evidence has been identified, other than in passing by the broadest of terms, how exactly the use of four prior art references lends an unobvious, patentable quality to the instantly claimed invention. It begs the question of how many references would be deemed acceptable by the appellant in the formulation of an obviousness prior art rejection based on more than one reference. It begins to become clear then, that the appellant is applying an overly stringent standard of prior art disclosure that is more in line with anticipation than with obviousness.

(C) In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the

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time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As explained above, the examiner has set forth a motivation for combining the prior art references of record in formulating the rejection of record based on obviousness. As explained above, a clear link between the four prior art references has been established by showing that they are all within the same field of endeavor and are broadly all concerned with solving the same general problem, that of wound healing. Therefore, despite the appellant's allegations against the selection of the references used in the prior art rejection of record, it is the position of the examiner that one of ordinary skill in the art would find the instantly claimed invention obvious in view of the collective disclosure of the prior art, would have a clear motivation to combine the references, and would have a reasonable expectation of success in doing so.

(D) In response to the appellant's argument concerning inherency, what was meant by the examiner was that a composition cannot stand apart from its properties. As the collective disclosure of the prior art has shown the instantly claimed invention, that is, partially carboxymethylated cellulose having fibrinogen, thrombin, and coagulation factor XIII bonded onto it via carbodiimide groups, it stands to reason that such cellulose material would exhibit the same attributes as claimed by the appellant, such as solubility and rapid dissolution.

(E) In response to the appellant's arguments concerning the declaration under 37 C.F.R. § 1.132 by Mr. Jo, the examiner does not dispute the results concerning the performance of the instantly claimed invention. However, in the opinion of the examiner, the declaration does not set forth a persuasive argument for patentability, as Mr. Jo has not accurately characterized the

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prior art in the sense that its collective disclosure has not been properly acknowledged. Mr. Jo has attacked the references on an individual basis and applied the standards for a prior art rejection made under the anticipation, as set forth in 35 U.S.C. 102 when the current prior art rejection has been made under obviousness, as set forth in 35 U.S.C. 103. The declaration does not address the obviousness of the motivation to combine the prior art references of record, as set forth above and in previous office actions. The analysis of the prior art references made by Mr. Jo is therefore incongruous with the actual prior art rejection that currently stands.

The examiner's reason for combining the references is not based upon the desire for performance along certain parameters, such as fibrinomer absorptivity, improved platelet agglutination, or improved adhered cell count. The examiner's reason for combining the references comes from the desire to achieve the objective of wound healing. The prior art need not recognize each and every beneficial property that may be present in the collective disclosure of the prior art. As explained above, as the prior art has broadly disclosed the instantly claimed invention, having the same structure and the same components, it would follow that the composition arising from this collective disclosure would also have the same properties as that claimed by the appellant, such as fibrinomer absorptivity, improved platelet agglutination, and improved adhered cell count.

(F) With regard to the arguments concerning Claims 36-40, 42, 43, and 46, it is the position of the examiner that the appellant's assessment of the prior art is incorrect. Specifically, the prior art does indeed teach chemical bonding of the proteins onto a support. The Sugitachi *et al.* patent discloses that coagulation proteins can be fixed onto a structure by covalent bonding, ionic bonding adsorption, or entrapping or immobilizing through conventional techniques (See

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Column 3, Lines 36-41). Furthermore, the Edwardson *et al.* patent teaches the immobilization of thrombin-like enzymes onto an activated support such as cellulose derivatives using various groups including carbodiimide groups (See Column 8, Line 56 to Column 9, Line 4; and Column 9, Lines 20-23 and 28). Therefore, the appellant has not clearly differentiated the invention embodied in Claims 36-40, 42, 43, and 46 from the collective disclosure of the prior art.

With regard to the arguments concerning Claims 44, 45, and 47, the Sugitachi *et al.* patent does indeed teach the use of a monofilament comprising coagulation proteins, which the examiner will interpret as sufficiently reading on the term “fiber” as recited in the claims (See Column 3, Lines 36-41). Furthermore, a process for pulverizing cellulose derivatives is disclosed in the prior art, in the Soe *et al.* reference, where it is crushed in a mortar (See Page 5, Section 0035). Again, as stated above, the appellant has not considered the disclosure of the prior art as a collective whole upon which the current prior art rejection is based, and has instead attacked each reference individually. Also, as stated above, as the prior art has broadly disclosed the same invention having the same structure with the same components, it then follows that such a composition arising out of the prior art would have the same properties as that disclosed by the appellant, including solubility.

With regard to the arguments concerning Claims 54, 55, and 57-66, it is the position of the examiner that the selection of appropriate processing parameters is well within the purview of one of ordinary skill in the art. Furthermore, it is also the position of the examiner that the appellant has not adequately shown how the selection of such parameters as claimed would impart a quality unto the instantly claimed invention that would yield results that are unexpected to one of ordinary skill in the art at the time the instantly claimed invention was made.

With regard to the arguments concerning Claims 49-52, as with the arguments concerning Claims 44, 45, and 47, since the prior art has broadly disclosed the same invention having the same structure with the same components, it then follows that such a composition arising out of the prior art would have the same properties as that disclosed by the appellant, including solubility. Regarding the recited limitations of intertwining in Claims 49 and 50, or specific denier in Claim 51, the appellant has not adequately shown how the selection of such parameters would yield results as it relates to wound healing that are unexpected to one of ordinary skill in the art at the time the instantly claimed invention was made. No results from comparative studies have been made of record thus far that would objectively show a patentable difference between the instantly claimed invention and the prior art.

With regard to the arguments concerning Claims 67-74, the examiner notes that arguments specifically addressing the patentability of these claims are not found in Argument 7(D) in the appellant's brief, or in any other portion of the brief. Nevertheless, as previously explained by the examiner, since the prior art has broadly disclosed the same invention having the same structure with the same components, it then follows that such a composition arising out of the prior art would have the same properties of performance as that disclosed by the appellant, including platelet agglutination rate, adhered cell count, and mean hemostasis time.

With regard to the arguments concerning Claims 41 and 48, as stated previously, the appellant has not considered the disclosure of the prior art as a collective whole upon which the current prior art rejection is based, and has instead attacked the Edwardson *et al.* patent as an individual reference. As the prior art rejection of record is based upon a combination of references, the disclosure of the prior art should be considered as a collective whole, which, in

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the view of the examiner, makes the instantly claimed invention obvious to one of ordinary skill in the art.

Despite the appellant's assertions that the claims are each individually patentable over the prior art, the appellant has failed to properly follow procedure in making a clear statement that the claims do not stand or fall together and giving reasons in support thereof.


For the above reasons, it is believed that the rejections should be sustained.

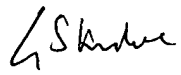
Respectfully submitted,

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